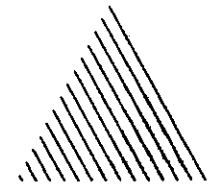
K081455

SEP - 5 2008



RAYNER
Surgical, Inc.

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510(k) Summary

Submitted by

Rayner Intraocular Lenses Ltd.

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Summary prepared on May 12th 2008

Device Name

- Trade/Proprietary Name: Rayner Single Use Small Incision Disposable Injector R-INJ-06
- Common Name: Rayner Single Use Small Incision Injector
- Classification Name: Product Code is MSS. CRF section is TITLE 21, Part 886, Subpart E, Sec. 886.4300 Intraocular lens guide. Device class is Class I. Classification Panel is Ophthalmic

Information on devices to which substantial equivalence is claimed

- 510(k) Number: K062512
- Trade or Proprietary or Model Name: Rayner Single Use Soft Tipped Disposable Injector R-INJ-04
- Manufacturer: Rayner Intraocular Lenses Ltd.

Intended Use

The single-use small incision disposable injector (model number R-INJ-06) is intended to be used to compress and insert into the capsular bag only those IOL models that allow use of this injector in their approved labeling.

Description of the device that is subject to of the application, including an explanation of how the device functions, basic scientific concepts, scientific physical and performance characteristics (design, material, physical properties)

The single-use small incision disposable injector (model number R-INJ-06) is intended to be used to compress and insert into the capsular bag only those IOL models that allow use of this injector in their approved labeling. It is designed to mechanically fold the lens and insert it into the eye during normal, small-incision cataract surgery.

INJECTOR LOADING is described as follows: aseptically transfer the injector to the sterile field by tipping it from the tray. Fully retract the plunger ensuring that the tip does not protrude into the loading bay. Open the loading bay flap fully to 90° and sparingly apply a commercially available viscoelastic inside the nozzle and to both grooves of the loading bay. Balanced salt solution alone should not be used as a lubricant. Carefully peel back the foil lid of the lens blister. Gently lift out the lens using parallel tipped, non-serrated forceps e.g. Kelman-McPherson. Rinse the IOL with sterile balanced salt solution. Position the lens in the loading bay in a "reverse - S" configuration. Ensure that the nearest edge of the optic is securely under the edge (lip) of the barrel. Hold open the flap and press down on lens with closed forceps to ensure the furthest edge of the optic is securely under the edge (lip) of the flap. Ensure the haptics are completely within the loading bay. While keeping the lens in position with open forceps, gently close the flaps of the injector ensuring that no part of the optic or haptics is trapped, before locking the flaps firmly together. Visually observe that the lens is symmetrically folded within the loading bay. Advance the plunger in a slow controlled manner. Anticipate an initial slight resistance. Excessive resistance could indicate a trapped lens. Observe that the lens stays symmetrically folded within the nozzle. When the lens exits the nozzle, stop depressing the plunger. The plunger is only to be depressed once.

The small incision injector (model number R-INJ-06) is a plastic, single-use disposable device.

The injector components barrel, flap, nozzle, bush and sleeve are made of polypropylene. The plunger is made of polycarbonate. The injector is transparent and the plunger is white.

Summary of how the technological characteristics of the device compare with the predicate device identified - Device comparison table:

Characteristics	Rayner Single Use Disposable Soft Tipped Injector R-INJ-04	Rayner Single Use Small Incision Disposable Injector R-INJ-06
Intended Use	Folds and delivers IOL into eye during normal small incision cataract surgery	Same
Operating Principle	- Load IOL into the inserter mechanically and insert IOL into the eye - IOL delivered by direct forward motion applied to a syringe type plunger	- Same - Same
Folding Operation	IOL is loaded into cartridge and closed. Opposing contact edges are folded towards each other	Same
Folding Direction of the Lens	Lens decompresses in a horizontal plane	Same
Cartridge design	None	None
Sterilization Method	EO for entire device	Same
Materials	Polypropylene barrel, flap, bush and nozzle. The plunger is polypropylene with a thermoplastic elastomer soft tip.	Polypropylene barrel, flap, bush, nozzle and sleeve. The plunger is polycarbonate.
Surface Treatment	None	None
Patient contact portion of the device	Nozzle and plunger tip	Same

Non-clinical performance data – discussion and conclusions

Substantial equivalence is based on the assessment of non-clinical performance data

More specifically this contains the following information:

- Biocompatibility testing on the injector
- Visual, optical and mechanical testing on injected IOL.
- Visual and mechanical testing on injector.
- Packaging performance testing

The performance data indicates that the Rayner Single Use Disposable Soft Tipped Injector R-INJ-06 delivers those IOL models, that allow use of this injector in their approved labeling, without significantly impacting the optical performance, the dimensions or the cosmetic appearance of the lens.

The following series of tests were conducted with the injection/lubrication media Balanced Salt Solution (BSS) and a viscoelastic currently approved and used on the US market.

a) Biocompatibility testing on the injector

Biocompatibility testing on the injector was undertaken on the nozzle and plunger tip as these components incorporate the materials in contact with the tissues of the eye. The injector components barrel, flap, bush and sleeve are made from the same polypropylene material as the nozzle. The nozzle was tested in a previous version of the single use disposable injector (model R-INJ-02 / K052651). The plunger is a polycarbonate material which was tested in a previous version of the single use disposable injector (model R-INJ-02 / K052651. The injector is transparent and the plunger is white. Using the scheme as outlined in ISO 10993-1 and the US Blue Book Memorandum G95-1 the following tests have been undertaken Cytotoxicity (Quantitative Growth Inhibition Test (ISO 10993-5), Maximization Test according to Magnusson and Kligman (ISO 10993-10) Intracutaneous Reactivity (ISO 10993-10) and Acute Systemic Toxicity (ISO 10993-11). Testing on the final packaged and terminally sterilized Single Use Disposable Injector shows the materials to be biocompatible/toxicologically safe for the intended clinical application (limited exposure duration with the device in contact with a breached/compromised surface).

b) Visual, optical and mechanical testing on injected IOL

VISUAL TESTING
Observation at magnification under optimal lighting conditions for the following:

- No optic lens tears for properly loaded lenses.
- No haptic damage.
- Absence of 'Fold lines' and/or deposits/debris on the lens surface.
- Evaluation of haptic fixation recovery time, to 11 mm diameter dimension.

OPTICAL TESTING

- Modulation Transfer Function
- Dioptric power
- Spectral transmittance

MECHANICAL TESTING

- Dimensions
- Lens sagittal dimension
- Lens overall diameter

- Haptic compression force

- Dynamic fatigue durability
- Limb/loop pull strength
- Optic decentration
- Optic tilt
- Axial displacement

The aforementioned mechanical testing is an assessment of the haptic function. Dioptric power does not affect the property tested. Therefore testing as per FDA IOL Guidance document Oct 10th 1997, was performed on 10 lenses each of both the highest and lowest powers.

Testing was carried out as per FDA guidelines in that the lens is folded for a minimum of 3 minutes. The IOL was allowed to return to its original and designed configuration. Compliance with applicable mechanical and optical requirements was demonstrated at 24+/-2 hours post folding/injection. (Reference ISO 11979-3, section 4.1 & CDRH IOL Guidance Document Oct 10th 1997).

c) Visual and mechanical testing on the single use disposable injector

VISUAL/PRODUCTION
- Surface finish & dimensional check

MECHANICAL
- Nozzle tip detachment from barrel/main body of injector

d) Packaging performance testing

The following tests were performed:
- Sterility test
- Dye penetration
- Burst Test

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2008

Rayner Surgical, Inc.
c/o Mr. Andrew Wells
Rayner Intraocular Lenses
6654 Church Street
Los Angeles, CA 90042-1555

Re: K081455
Trade/Device Name: Rayner Single Use Small Incision Disposable Injector R-INJ-06
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I
Product Code: MSS
Dated: August 8, 2008
Received: August 13, 2008

Dear Mr. Wells:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081455

Device Name: **Rayner Single Use Small Incision Disposable Injector R-INJ-06**

Indications For Use:

Statement of Indications for use

"The single-use small incision disposable injector (model number R-INJ-06) is intended to be used to compress and insert into the capsular bag only those IOL models that allow use of this injector in their approved labeling."

Prescription Use ✓ Yes__ AND/OR Over-The-Counter Use __No.____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation ~~(ODE)~~

Mridula Virmani 9/3/08

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K081455